

## Part I Overview Information

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### United States Department of Health and Human Services (HHS)

#### Issuing Organization

Centers for Disease Control and Prevention (CDC) at <http://www.cdc.gov>

#### Participating Organizations

Centers for Disease Control and Prevention (CDC) at <http://www.cdc.gov>  
National Institutes of Health (NIH) at [www.nih.gov](http://www.nih.gov)

#### Components of Participating Organizations

Centers for Disease Control and Prevention, National Centers for Chronic Disease Prevention and Health Promotion (CDC/NCCDPHP) at <http://www.cdc.gov/nccdphp>  
National Institutes of Health/National Cancer Institute at <http://www.cancer.gov>

### **Title:** Knowledge Synthesis Center for Evaluating Genomic Application in Practice and Prevention (U18)

The policies, guidelines, terms, and conditions of the HHS Centers for Disease Control and Prevention (CDC) stated in this announcement might differ from those used by the HHS National Institutes of Health (NIH). If written guidance for completing this application is not available on the CDC website, then CDC will direct applicants elsewhere for that information. [NOT APPLICABLE]

CDC and NIH will be collaborators for this project. The policies, guidelines, terms, and conditions of the HHS Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) must be followed.

#### **Authority:**

This program is authorized under section 317(k)(2) of the Public Health Service Act (PHS Act), 42 U.S.C., 247b(k) (2); Section 301(a) of the PHS Act, 42 U.S.C 241(a).

#### **Announcement Type: New**

#### **Instructions for Submission of Electronic Research Applications:**

**NOTICE:** Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide.

This FOA must be read in conjunction with the application package instructions included with this announcement on [Grants.gov/Apply](http://Grants.gov/Apply) for Grants (hereafter referred to as, Grants.gov/Apply.)

A registration process is necessary before submission, and applicants are strongly encouraged to start the process at least four weeks prior to the grant submission date. See [Section IV](#).

**Two steps are required for on time submission:**

- 1) The application must be successfully received by Grants.gov no later than 5:00 p.m. Eastern Standard Time on the application submission receipt date (see “[Key Dates](#)” below.)
- 2) Applicants must complete a verification step in the Electronic Research Administration (eRA [Commons](#)) within two business days of notification. Note: Since email can be unreliable, it is the responsibility of the applicant to periodically check on their application status in the eRA [Commons](#).

**Funding Opportunity Announcement (FOA) Number:**

**RFA-GD10-001**

**Catalog of Federal Domestic Assistance Number(s):**

**93.068** Chronic Diseases: Research, Control and Prevention.

**Key Dates**

Release/Posted Date: January 29, 2010  
Letter of Intent Receipt Date: March 1, 2010  
Application Submission Receipt Date(s): April 07, 2010  
Peer Review Date(s): May 2010  
Council Review Date(s): June 2010  
Earliest Anticipated Start Date(s): September 15, 2010  
Expiration Date: April 1, 2010

**Due Date for E.O. 12372**

Executive Order 12372 does not apply to this program.

**Additional Overview Content**

## Executive Summary

- This RFA Funding Opportunity Announcement (FOA) solicits research demonstration cooperative agreement (U18) applications to fund a Genomics Knowledge Synthesis Center. The Center will conduct, update, and publish systematic evidence reviews to address selected questions for the evaluation of a set of health-related genomic tests that may include DNA, RNA, and proteomic tests; family health history tools; and and/or other health-related genomic services (“genomic applications”). The Center will also produce brief narrative information summaries (“topic briefs”) on the validity and utility of selected genomic applications and related issues. Reviews and briefs will be integrated into an online knowledge repository for Genomic Applications in Practice and Prevention (GAPP) that CDC is developing in collaboration with the National Cancer Institute (NCI) and the National Center for Biotechnology Information (NCBI) of the National Library of Medicine. Research supported by this RFA will advance knowledge about what is known, and needs to be known, about the validity and utility of genomic applications for improving health and preventing disease.
- CDC intends to commit approximately \$500,000 in total costs (direct and indirect) in FY2010, 1.5 million over 3 years, to fund one (1) application (award).
- The award issued under this RFA is contingent upon the availability of funds and the submission of meritorious applications.
- Anticipated number of awards to be issued under this RFA in FY 2010: one (1).
- Budget Period, Project Period, and Award Amounts: The maximum award to support direct and indirect costs range for the first 12-month budget period is \$500,000. The total project period for applications submitted in response to this RFA is three years.
- Eligible Organizations: Public nonprofit organizations; private nonprofit organizations; for profit organizations; small, minority, and women-owned businesses; universities; colleges; research institutions; hospitals; community-based organizations; faith-based organizations; federally recognized or state-recognized American Indian/Alaska Native tribal governments; American Indian/Alaska Native tribally designated organizations; Alaska Native health corporations; urban Indian health organizations; tribal epidemiology centers; state and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau); and political subdivisions of states (in consultation with states.) A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide required documentation from the state or local government as documentation of your status. Attach this documentation behind

the first page of your application form or for electronic applications, use a PDF file and attach as “Other Documents” and label as appropriate.

- See Section IV.1 for application materials. The SF424 (R&R) Application Guide for this FOA is located at these Web sites:  
[http://grants1.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General.doc](http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.doc) (MS Word); [http://grants1.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General.pdf](http://grants1.nih.gov/grants/funding/424/SF424_RR_Guide_General.pdf) (PDF)
- For general information on SF424 (R&R) Application and Electronic Submission, see these the following Web sites: SF424 (R&R) Application and Electronic Submission Information: <http://grants.nih.gov/grants/funding/424/index.htm>; General information on Electronic Submission of Grant Applications: <http://era.nih.gov/ElectronicReceipt/>
- HHS/CDC Telecommunications for the hearing impaired is available at the following number: TTY 770-488-2783.

## **Funding Opportunity Announcement Glossary: FOA Glossary Terminology**

### **Table of Contents**

---

Part I Overview Information

Part II Full Text of Announcement

Section I. Funding Opportunity Description

1. Research Objectives

Section II. Award Information

1. Mechanism(s) of Support  
2. Funds Available

Section III. Eligibility Information

1. Eligible Applicants  
A. Eligible Institutions  
  
2. Cost Sharing or Matching  
3. Other - Special Eligibility Criteria

Section IV. Application and Submission Information

1. Request Application Information  
2. Content and Form of Application Submission  
3. Submission Dates and Times  
A. Receipt and Review and Anticipated Start Dates  
1. Letter of Intent  
B. Submitting an Application to CDC  
C. Application Processing  
4. Intergovernmental Review  
5. Funding Restrictions  
6. Other Submission Requirements

Section V. Application Review Information

1. Criteria
2. Review and Selection Process
  - A. Additional Review Criteria
  - B. Additional Review Considerations
  - C. Sharing Research Data
  - D. Sharing Research Resources
3. Anticipated Announcement and Award Dates

#### Section VI. Award Administration Information

1. Award Notices
2. Administrative and National Policy Requirements
  - A. Cooperative Agreement
    1. Recipient Rights and Responsibilities
    2. HHS/CDC Responsibilities
    3. Collaborative Responsibilities
3. Reporting

#### Section VII. Agency Contact(s)

1. Scientific/Research Contact(s)
2. Peer Review Contact(s)
3. Financial/ Grants Management Contact(s)
4. General Questions Contact(s)

#### Section VIII. Other Information - Required Federal Citations

## Part II - Full Text of Announcement

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### Section I. Funding Opportunity Description

#### 1. Research Objectives

The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) of CDC within HHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010" and to measuring program performance as stipulated by the Government Performance and Review Act (GPRA). This RFA addresses "Healthy People 2010" priority area(s) of arthritis, cancer, kidney disease, diabetes, disability, heart disease and stroke, HIV, infectious diseases, maternal and child health, mental health, overweight, respiratory diseases, substance abuse, tobacco use, vision and hearing, educational and community-based programs, and/or public health infrastructure, and is in alignment with NCCDPHP performance goals. For more information, [www.healthypeople.gov](http://www.healthypeople.gov), and <http://intra-apps.cdc.gov/fmo/>

#### Nature of the Research Opportunity

Systematic reviews of knowledge about genomic applications are needed to move human genomics research into clinical and public health practice in ways that maximize health benefits and minimize harms to individuals and to populations. Easily accessible, web-available evidence reviews and topic briefs on what is known and needs to be learned

about the validity and utility of genomic applications are important for public health and clinical practitioners and researchers, for groups that make evidence-based guidelines and recommendations about the use of genomic applications, and for policy makers and other stakeholders interested in the responsible translation of new knowledge in genomics into practice. This FOA solicits applications to establish a Genomics Knowledge Synthesis Center to conduct, update, and publish systematic evidence reviews to evaluate selected health-related genomic tests including DNA, RNA, and proteomic tests; family health history tools; and other health-related genomic services (“genomic applications”). These reviews will examine specific sets of questions related to the analytic validity, clinical validity, and/or clinical utility of the genomic applications as well ethical and social issues (ELSI) involved in their use. The Center will also produce brief narrative information summaries (“topic briefs”) on selected genomic applications and reports on how to do evidence reviews and topic briefs.. Final versions of evidence reviews and topic briefs will be deposited at the NCBI and made available on the NCBI public website, although they may also appear on other sites or in publications as appropriate.

## **Background**

The translation of basic genomic information into clinical and public health services has proceeded at a rapid pace since the Human Genome Project was completed in 2003. As of mid-2009, genetic tests for more than 1,700 diseases have been developed, and more than 1,400 are available for clinical use (<http://www.ncbi.nlm.nih.gov/sites/GeneTests>). While most genetic tests are used in the diagnosis of rare, single gene disorders, a growing number of genomic tests have the potential for much broader use, including predictive testing to assess risk for common diseases, and pharmacogenetic testing aimed at predicting an individual’s response to certain drugs. Along with rapid growth in the availability of genetic tests over recent years, more tests are being offered directly to consumers (DTC), with promotion via the Internet and other media outlets. Similarly, interest and use of family health history is increasing, and the U.S. Surgeon General has made a tool available for collection of family history information for individuals to take to their health care providers (<https://familyhistory.hhs.gov/fhh-web/home.action/>). The Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) has found that oversight and regulation of genetic test development in the U.S. is complex, with many groups involved, and leaves major gaps in oversight that could lead to harms ([http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_oversight\\_report.pdf](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf)). While many view advances in genomic research and technology as signs heralding the beginning of an age of personalized medicine, questions remain about the validity and utility of many tests currently available (<http://journals.lww.com/geneticsinmedicine/toc/2009/08000>). In addition, given gaps and the uncertainty in the oversight and lack of consensus on a process for developing and evaluating genomic applications, it is also possible that valid and useful genomic applications may not be effectively translated into practice because of lack of certainty about benefit.

Developing clinical and public health services from basic genomic discoveries is the first step along a translation continuum leading to the ultimate goal of understanding health

impact on a population level (Genet Med 2007;9(10):665-674). Currently there are abundant data available from early phase studies; however, little research has been conducted on the utility of tests, how to get useful tests implemented, and evaluating the impact of test use on population health. Clinical and public health practitioners, the public, policy makers and other stakeholders need reliable information on what is known about benefits and risks associated with particular tests (Hudson K. Health Affairs 2008;27(6)1612-5). Agencies developing healthcare policy need this type of information to inform decisions so that healthcare dollars can be spent most effectively (<http://www.iom.edu/CMS/3809/28393.aspx>).

In 2004, OPHG established a non-regulatory initiative known as Evaluation of Genomic Applications in Practice and Prevention (EGAPP) to develop and test methods for assessing available evidence on genomic services in healthcare (<http://www.cdc.gov/genomics/gtesting/EGAPP/index.htm>). The EGAPP Working Group (EWG), a multidisciplinary panel of non-federal experts, has developed methods for evaluation of the new genetic tests and related technologies in order to make recommendations for use based on the evidence (<http://www.egappreviews.org/workinggrp/methods.htm>). The Working Group has published recommendations on the use of four different tests, for individuals newly diagnosed with depression or with cancer (<http://www.egappreviews.org/workinggrp/recommendations.htm>). Additional recommendations are currently being developed. Response by many stakeholders to EGAPP has been positive. For example, in 2008, the SACGHS Secretary's Advisory Committee on Genetics, Health and Society acknowledged EGAPP as an approach to assessing clinical utility of tests ([http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_oversight\\_report.pdf](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf)) and in 2009 the Medicare Evidence Development and Coverage Advisory Committee, an independent CMS advisory group, recommended that CMS make use of EGAPP methods in evaluating new tests to help make Medicare coverage decisions (<http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?from2=viewdraftdecisionmemo.asp&id=224&/>).

The Agency for Healthcare Research and Quality and the U.S. Preventive Services Task Force have also developed methods for evaluating genomic applications, including family history, and published methods papers, reviews, and recommendations (<http://www.ahrq.gov/clinic/>).

In 2009, OPHG, the NCI, and other partners initiated a Genomic Applications in Practice and Prevention Network (GAPPNet) (<http://www.cdc.gov/genomics/translation/GAPPNet/index.htm>) to bring together researchers, practitioners, and other stakeholders in the development and use of genomics applications. The purpose of GAPPNet is to increase communication, coordination and collaboration among stakeholders to accelerate the process of responsibly translating valid and useful genomic knowledge and applications into practice.

As part of the GAPPNet process, CDC will develop an online GAPP Knowledge Repository with brief summaries and links to evidence reviews and recommendations and other information sources about genomic applications in transition to practice. This

knowledge repository addresses a recommendation made by SACGHS that an online registry or repository of information be made available on the web to provide accurate and current information for tests currently on the market.

([http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_oversight\\_report.pdf/](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_oversight_report.pdf/))

Recently Javitt et al, proposed a blueprint for a registry that identified critical elements for the registry, including information on the analytic and clinical validity of the tests. (<http://content.karger.com/ProdukteDB/produkte.asp?doi=10.1159/000226593/>). The Division of Cancer Control and Population Sciences at NCI is collaborating with CDC to support knowledge synthesis for GAPPNet and has committed funding to CDC for this announcement. The National Center for Biotechnology Information (NCBI) of the National Library of Medicine is partnering with CDC to support this announcement and the linkage of other information sources to the CDC supported genomics applications knowledge repository. Final versions of evidence reviews and topic briefs will be deposited at the NCBI and made available on the NCBI public website, although they may also appear on other sites or in publications as appropriate.

## **Scientific Knowledge to be Achieved through this Funding Opportunity**

Developing clinical and public health services from basic genomic discoveries is the first step along a translation continuum leading to the ultimate goal of understanding health impact on a population level. Successful genomic applications will move human genomics research into clinical and public health practice in ways that maximize health benefits and minimize harms to individuals and to populations.

## **Research Objectives and Experimental Approach**

### **1. Funding the Genomics Knowledge Synthesis Center**

This announcement will fund a Genomics Knowledge Synthesis Center to plan and conduct three types of scientific activities: 1) developing systematic evidence reviews on selected genomic applications, 2) creating topic briefs on genomic applications, 3) and developing methods to enhance the efficiency and quality of systematic evidence reviews. These reviews will examine the validity and utility of health-related genomic applications, contextual factors, and ELSI issues using methods and procedures developed by the EGAPP Working Group and CDC during the last 5 years. The Center will conduct literature, internet and other searches to collect information from published, unpublished, and “gray literature” sources. The Center and CDC will systematically evaluate the quality of information and will synthesize and summarize the information using methods developed by EGAPP. The Center, working collaboratively with CDC, will develop brief narrative summaries of available information (topic briefs). The Center, in collaboration with CDC and with input from the EGAPP Working Group, may also develop methods for statistical and decision modeling. Some reviews will be used by the EGAPP Working Group to make additional recommendations on genomic tests and

other services. The Center will also collaborate with CDC to contribute reviews and brief summaries to the online GAPP knowledge repository for GAPPNet.

Applicants should demonstrate the capacity and experience of their host organization and their team to meet these complex requirements. Participating organizations should have an existing operating organizational infrastructure, including financial management and contracting capabilities; physical capacity, such as office space; and other informational resources sufficient to support the Knowledge Synthesis Center.

In addition, applicants should demonstrate that their project team includes individuals who have successfully: 1) led a project team to conduct systematic evidence reviews of the analytic validity, clinical validity, and clinical utility of diagnostic, screening, or risk assessment tests/tools for clinical use, 2) evaluated genomic applications and clinical tests and 3) conducted statistical and/or clinical epidemiologic analysis. The grant application and CVs of applicants must provide documentation of this experience, including previous funding and/or peer-reviewed publications in these areas. Applicants who have provided a complete citation and abstract in section III.3 of a systematic evidence review, published or accepted for publication in a peer-reviewed journal, for which the principal investigator or one of the key personnel is the first author may refer to the citation as evidence of specialized experience.

Finally, applicants should provide step-by-step descriptions of the general approach they will take toward accomplishing each of the next four objectives.

## **2. Systematic Evidence Reviews**

### **Objective**

It is anticipated that each year two (2) to six (6) systematic evidence reviews will be completed and posted on the GAPP knowledge repository. The number of reviews will depend on the scope of the reviews, the number of evaluation questions each review addresses, and the number of articles and other sources of information reviewed. The scope and complexity of the evidence reviews will vary depending on the definition of the genomic application; the set of validity, utility, contextual, and ELSI questions to be addressed; the depth of the search for information; and the amount of literature and other information available. Decisions about scope and questions to be addressed in the review will be made by CDC, a Technical Expert Panel, which may include members of the EGAPP Working Group, and the Center based on needs and recommendations from the EGAPP Working Group, GAPPNet, and other stakeholders.

### **Methods**

Topic selection will be based on requests from the EGAPP Working Group and recommendations from GAPPNet and other stakeholders.

Systematic evidence reviews will be conducted for specific genetic tests or other genomic applications topics using EGAPP methods (Genet Med 2009:11(1):3-14).

Potential questions about the genomic applications for which evidence will be reviewed include those identified by the CDC Analytic Validity, Clinical Validity, Clinical Utility, and Ethical, and Social Implications (ACCE) project (<http://www.cdc.gov/genomics/gtesting/ACCE/index.htm>). The assessment of analytic validity involves an evaluation of the accuracy and reliability of the tests in detecting genomic markers of interest. Clinical validity assessment examines the accuracy and reliability of a test in predicting a disorder or phenotype of interest, for example risk of disease or drug response. The Human Genome Epidemiology Navigator may serve as an initial source of information on research on gene-outcome relationships (<http://hugenavigator.net/>). Evaluation of clinical validity commonly includes an assessment of validation and calibration studies and assessments of the sensitivity, specificity, predictive values, the area under the receiver operating characteristic curve, and numbers needed to screen/assess/diagnose to identify a single individual with the condition. Assessments for genomic applications used for screening and/or risk prediction may include assessments of the ability of the genomic application to estimate absolute risk. In addition, the ability of the application to classify individuals according to relevant published clinical guidelines for medical intervention, such as the risk classifications using the Framingham score used for clinical decision making, may be examined. Assessment of clinical utility involves the evaluation of evidence of improved health outcomes from use of a test and related interventions and the utility of test information in clinical decision-making. ELSI issues include such topics as implications, family or social issues, and safeguards. Contextual Issues, which may also be addressed, include considerations such as clinical alternatives and cost effectiveness.

The scope and complexity of the evidence reviews will vary depending on the definition of the genomic application; the set of validity, utility, contextual, and ELSI questions to be addressed; the depth of the search for information; and the amount of literature and other information available. Decisions about scope and questions to be addressed in the review will be made by CDC and the Center based on needs and recommendations from the EGAPP Working Group, GAPPNet, and other stakeholders. For example, for new topics taken up by the EGAPP Working Group for which no evidence reviews have been completed previously, a complete review of all questions identified by the EGAPP Working Group and ACCE will be needed (Genet Med 2009:11(1):3-14; <http://www.cdc.gov/genomics/gtesting/ACCE/index.htm>). Alternatively, when an already published review exists, a supplementary review may be conducted to provide more information to the Working Group or to address issues not clearly identified in the previously published review (<http://www.egappreviews.org/workinggrp/reports.htm>). Reviews of specific sets of questions will also be needed to address research gaps identified in the earlier reviews and recommendation statements.

For reviews addressing the complete range of questions from analytic validity through ELSI and contextual factors, detailed methods outlined in the EGAPP Working Group Methods paper are used and efforts are made to construct and evaluate a chain of evidence that links the disorder, service, and scenario with health outcomes. The objective of the reviews is a comprehensive evaluation, integration, interpretation, and summary of the available evidence, rather than a summary description of relevant studies.

Examples of such reviews are easily accessible and can be downloaded at the EGAPP Working Group web site (<http://www.egappreviews.org/workingrp/reports.htm/>). These include reviews on genetic testing in adults with a history of thromboembolism, testing for Lynch syndrome (hereditary nonpolyposis colorectal cancer), the impact of breast cancer gene expression profiling on health outcomes, testing for cytochrome P450 polymorphisms in adults newly diagnosed with non-psychotic depression prior to treatment with selective serotonin reuptake inhibitors, and genomic tests for ovarian cancer detection and management.

In general, for detailed reviews, the following steps are taken:

1. carefully defining the topic for review, based on the medical disorder, the specific genomic application, and clinical scenario for use of the service;
2. developing an analytic framework and framing the specific questions for which evidence is collected and reviewed, including questions related to the analytic validity, clinical validity, and clinical utility of the service, contextual factors, ELSI issues, and both benefits and harms;
3. gathering technical experts and reviewers;
4. identifying data sources and searching for evidence using explicitly stated strategies and study inclusion/exclusion criteria;
5. specifying criteria for assessing quality of studies and conducting the assessment;
6. abstracting data into evidence tables;
7. synthesizing findings;
8. conducting clinical decision modeling studies as needed to address issues for which data are not conclusive;
9. conducting economic analyses as needed for evaluation of contextual issues;
10. evaluating the overall quality of evidence related to the analytic framework or “chain of evidence;”
- 11; assessing the overall balance of benefits and harms from using the test based on available evidence and information from modeling studies; and
12. identifying gaps in knowledge and identifying research questions for which research is most needed.

Test developers and researchers may need to be contacted to request additional information, primarily about analytic validity, when it cannot be found in the public domain.

More detailed descriptions and definitions of these steps is available in the EGAPP Working Group Methods paper (<http://www.egappreviews.org/workingrp/methods.htm>)

For reviews targeting a limited set of questions, most of the steps and methods noted above will be used in the assessment. However, some steps and details will not be necessary because of the more limited scope of the questions and/or the use of already available reviews.

To assure a transparent and open process and opportunity to improve quality of reviews, a number of steps will be taken. The analytic framework and key questions will be posted on the CDC web site for external comment and possible revision. After a review is completed, it will be distributed to the TEP, other selected expert reviewers, including possibly GAPPNet collaborators and the EGAPP Working Group for peer review. Names of reviewers, anonymized comments on the report, and responses to comments will be posted on the GAPPNet web site. Final reports and summary manuscripts will be developed incorporating responses to comments. Reviews conducted for the EGAPP Working Group will need EGAPP Working Group approval.

Evidence reviews will be posted on the GAPP knowledge repository. and comment will be solicited. Questions and comments from a variety of stakeholders using a variety of methods will be collected. The format and content of the reviews may be revised based on feedback from web page users and from other stakeholders.

Applicants should provide a conceptual workplan for completing systematic reviews which will:

- describe details of the specific steps investigators will follow to complete systematic reviews;
- show the relationship between these activities and the EGAPP framework cited above;
- indicate the time required for each step and the expected time required to complete a review;
- describe any unique aspects of their plan which will create efficiencies or provide some special capacity to use the review for multiple purposes;
- provide a staffing plan describing each team member's training, expertise and role in carrying out this objective and describing how the team members will complement each other's skills and work together.

Applicants may include completed systematic reviews as evidence of their capacity (please indicate the appendix location of this exhibit).

### **3. Topic Briefs**

#### **Objective**

It is anticipated that 20 – 30 new topic briefs will be created and posted on the GAPPNet knowledge repository each year and that all posted briefs will be updated annually.

Given the large number of genomic applications being made available to providers and the public and the fact that systematic evidence reviews cannot be provided for all of them, very brief information products (topic briefs) will also be developed based on a non-systematic, brief review of available information. These topic briefs are short (1-2 pages) narrative summaries of readily available information.

The topic brief first identifies the clinical scenario for the genomic application, including the genomic test or other application, the medical disorder for which the application is intended, and the proposed use of the test. The brief then summarizes what is known

from a limited search of the published literature, “gray literature,” the FDA and other web sites, and other public sources. The summaries will focus on what is known about the analytic validity, clinical validity, and clinical utility of the applications. The brief includes links to any published evidence reviews and recommendations from other groups. Selected information about the public health importance of topic, contextual, ethical, , or social issues and critical research gaps may be included.

## **Method**

Topics for the briefs developed under this announcement will be selected by the CDC in collaboration with the Center, the EGAPP Working Group and GAPPNet stakeholders based on a number of criteria including strong stakeholder interest, potential for common utilization, and potential for health impact.

The process for developing the topic briefs involves the following steps:

1. defining the topic for review, based on the medical disorder, the specific genomic application, the proposed purpose of the test, and clinical scenario for use of the service;
2. identifying information sources and searching for evidence using explicitly stated strategies and study inclusion/exclusion criteria;
3. specifying criteria for assessing quality of information sources and excluding uninformative sources;
4. summarizing information into a short statement about findings related to analytic validity, clinical validity, and clinical utility as well as selected public health, contextual, ethical, , social issues or critical research gaps;

For topic briefs, no overall assessment of the quality of evidence is provided and no judgments are made about the validity and/or utility of the genomic application.

Examples of topic briefs are available on the CDC GAPPNet web page ([www.cdc.gov/genomics/gtesting/topicbriefs/index.htm](http://www.cdc.gov/genomics/gtesting/topicbriefs/index.htm)).

Topic briefs will be posted on the GAPP knowledge repository and comment will be solicited. Format and content of future topic briefs may be revised.

Applicants should provide a conceptual workplan for completing topic briefs which will:

- describe details of the specific steps investigators will follow to complete systematic reviews;
- provide a staffing plan describing each team member’s training, expertise, and role in carrying out this objective and describing how the team members will complement each other’s skills and work together;
- indicate the time required for each step and the expected time required to complete a review;
- describe any unique aspects of their plan which will create efficiencies or provide some special capacity to complete topic briefs.

Applicants may include in the appendices brief public health communication products completed by key personnel as evidence of their capacity (please indicate the appendix location of these exhibits).

#### **4. Methods development**

##### **Objective**

Research will be conducted to develop additional procedures and methods to build upon those previously developed by the EGAPP Working Group (Genet Med 2009;11(1):3-14), and it is anticipated that one methods paper will be completed during the three year period. In year 2, the Center will collaborate with CDC to develop and complete detailed procedure manuals for conducting systematic evidence reviews for the EGAPP Working Group and for developing topic briefs.

Given that the evaluation of genomic applications is a relatively new endeavor, new methods that build upon existing EGAPP methods are needed. Complete reviews typically take a year or more to conduct. Stakeholders such as practicing clinicians and insurers often need information much more quickly and need more information than is available in a topic brief. Burke and Zimmern as well as Gudgeon and colleagues as well as others have proposed methods for “rapid reviews” (<http://www.phgfoundation.org/pages/work7.htm>) and (<http://www.ncbi.nlm.nih.gov/pubmed/17666894>). Examples of such reviews are available (<http://www.ncbi.nlm.nih.gov/pubmed/18281915>). However, detailed methods for “rapid reviews” are not available and the adequacy of such reviews for evidence-based recommendations by groups such as the EGAPP Working Group and the U.S. Preventive Services Task Force has not been evaluated. Methods for conducting such reviews need to be developed and evaluated. In addition, methods are needed for doing early stage assessments of genomic applications using clinical decision modeling techniques with a structured approach to synthesize quantitative factors such as gene prevalence, test performance characteristics, and likelihood of disease outcomes (<http://www.ncbi.nlm.nih.gov/pubmed/17697328?dopt=AbstractPlus>).

Decisions on topics for methods development will be made by CDC and the Center based on the Center’s experience and interests, needs, and recommendations from the EGAPP Working Group, GAPPNet and other stakeholders.

Applicants should provide evidence of their capacity to plan and complete innovative methods research. Applicants should discuss the relevant backgrounds and experience of the project team, relevant prior research (citations included in the appendix should be noted), and their overall research approach to conducting methods research.

##### **Methods**

Applicants should propose a plan and timeline for completing detailed procedure manuals. While applicants will be expected to incorporate existing EGAPP working

group methodologies in the manual, they are also encouraged to propose creative approaches for leveraging their existing resources to produce effective self-guided instructional manuals.

Resources:

Following is a list of resources to guide in the development of research projects submitted in response to this FOA:

Web links to resources on the following:

EGAPP methods (<http://www.egappreviews.org/workingrp/methods.htm>)

EGAPP reviews (<http://www.egappreviews.org/workingrp/reports.htm>)

EGAPP recommendations

(<http://www.egappreviews.org/workingrp/recommendations.htm>)

USPSTF methods (<http://www.ahrq.gov/clinic/uspstmeth.htm>)

USPSTF recommendations and reviews (<http://www.ahrq.gov/clinic/cps3dix.htm>)

CDC Topic Briefs: ([www.cdc.gov/genomics/gtesting/topicbriefs/index.htm](http://www.cdc.gov/genomics/gtesting/topicbriefs/index.htm))

GAPP knowledge repository

:(<http://www.cdc.gov/genomics/translation/GAPPNet/functions.htm#knowledge>)

See Section VIII, Other Information - Required Federal Citations, for policies related to this announcement.

## **Section II. Award Information**

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### **1. Mechanism(s) of Support**

This funding opportunity will use the U18 activity code.

The HHS/CDC U18 is a cooperative agreement assistance instrument. Under the U18 assistance instrument, the Recipient Organization retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, and with HHS/CDC staff is substantially involved as a partner with the Recipient Organization, as described in Section VI.2.A., "Cooperative Agreement".

### **2. Funds Available**

The participating Centers, Institutes and Offices (CIO)(s), NCCDPHP/OPHG and NCI/DCCPS, intend to commit approximately \$500,000 in total costs (direct and indirect costs) for the first 12-month budget period in FY2010 to fund one (1) application. The

average award amount will be \$350,000 to \$500,000 (direct and indirect costs) for the first 12-month budget period. An applicant may request a project period of up to three (3) years. An applicant may request up to \$500,000 for the first 12-month budget period. The approximate total project period funded amount is \$1.2 million to \$1.5 million in total costs. The anticipated start date for new awards is September 30, 2010.

If an applicant requests a funding amount greater than the ceiling of the award range, HHS/CDC will consider the application non-responsive, and it will not enter into the review process. HHS/CDC will notify the applicant that the application did not meet the submission requirements.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary. Although the financial plans of the CIO (s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

Facilities and Administrative (F&A) costs requested by consortium participants are not included in the direct cost limitation. See [NOT-OD-05-004](#).

## **Section III. Eligibility Information**

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### **1. Eligible Applicants**

#### **1.A. Eligible Institutions**

- Public nonprofit organizations
- Private nonprofit organizations
- For profit organizations
- Small, minority, and women-owned businesses
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized or state-recognized American Indian/Alaska Native tribal governments
- American Indian/Alaska Native tribally designated organizations
- Alaska Native health corporations
- Urban Indian health organizations
- Tribal epidemiology centers
- State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the

Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

- Political subdivisions of States (in consultation with States)

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Attach this documentation behind the first page of your application form or for electronic applications, use a PDF file and attach as “Other Documents” and label as appropriate.

## 2. Cost Sharing or Matching

This program does not require cost sharing or matching funds

The most current HHS Grants Policy Statement is available at:  
[http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc)

## 3. Other-Special Eligibility Criteria

a. Applicants must have significant experience in conducting systematic evidence reviews and/or applied genomics research. To demonstrate prior experience, applicants should include in the appendices one or both of:

1) the complete citation and abstract of a systematic evidence review, published or accepted for publication in a peer-reviewed journal, for which the principal investigator or one of the key personnel is the first author.

2) the complete reference and abstract for a funded applied genomics study supported by NIH, another Federal agency, or a major not-for-profit funding agency for which the principal investigator or one of the key personnel was the PI.

Please indicate the location of these citations in the appendices.

b. Project teams must include an experienced clinical or medical geneticist. Please identify this person in this section and include their CV in the staffing section.

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not enter into the review process.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

## Section IV. Application and Submission Information

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To download a SF424 (R&R) Application Package and SF424 (R&R) Application Instructions for completing the SF424 (R&R) forms for this FOA, link to [Grants.gov/Apply](https://www.Grants.gov/Apply) and follow the directions provided on that Web site.

A one-time registration is required for institutions/organizations at the following:

- Grants.gov Get Registered, [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)
- eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

**IMPORTANT:** both the applicant organization, as well as, the PD/PI must register in eRA Commons for an application to be accepted electronically. The Credentials Log-In, referenced in Section IV. 2. Content and Form of Application Submission, is obtained through Step #3 in the required actions below.

PD/PIs should work with their institutions/organizations to make sure they are registered in the eRA Commons.

The following three steps are required before an applicant institution/organization can submit an electronic application, as follows:

1) Organizational/Institutional Registration in Grants.gov Get Registered, [http://www.grants.gov/applicants/get\\_registered.jsp](http://www.grants.gov/applicants/get_registered.jsp)

- Your organization will need to obtain a [Data Universal Number System \(DUNS\) number](#) and register with the [Central Contractor Registration \(CCR\)](#) as part of the Grants.gov registration process.
- If your organization does not have a Taxpayer Identification Number (TIN) or Employer Identification Number (EIN), allow for extra time. A valid TIN or EIN is necessary for CCR registration.
- The CCR also validates the EIN against Internal Revenue Service records, a step that will take an additional one to two business days.
- **If Foreign Institutions are listed in Section III.1.A. Eligible Institutions, include the following bullet:** Applicants outside the US are required to include a NATO Commercial and Government Entity (NCAGE) number on their CCR registration. See section IV.2. Content and Form of Application Submission, for instructions.
- Direct questions regarding Grants.gov registration to:  
[Grants.gov Customer Support](#)  
Contact Center Phone: 800-518-4726  
Business Hours: M-F 7:00 a.m. - 9:00 p.m. Eastern Time  
Email [support@grants.gov](mailto:support@grants.gov)

2) Organizational/Institutional Registration in the eRA Commons Prepare to Apply, <http://era.nih.gov/ElectronicReceipt/preparing.htm>

- To find out if an organization is already eRA Commons-registered, see the "[List of Grantee Organizations Registered in eRA Commons.](#)"
- Direct questions regarding the eRA Commons registration to:  
eRA Commons Help Desk  
Phone: 301-402-7469 or 866-504-9552 (Toll Free)  
TTY: 301-451-5939  
Business hours M-F 7:00 a.m. – 8:00 p.m. Eastern Time  
Email [commons@od.nih.gov](mailto:commons@od.nih.gov)

3) Project Director/Principal Investigator (PD/PI) Registration in the eRA Commons: Refer to the [NIH eRA Commons System \(COM\) Users Guide](#).

- The individual designated as the PD/PI on the application must also be registered in the eRA Commons. It is not necessary for PDs/Pis to register with Grants.gov.
- The PD/PI must hold a PD/PI account in the eRA Commons and must be affiliated with the applicant organization. This account cannot have any other role attached to it other than the PD/PI.
- This registration/affiliation must be done by the Authorized Organization Representative/Signing Official (AOR/SO) or their designee who is already registered in the eRA Commons.
- Both the PD/PI and AOR/SO need separate accounts in the eRA Commons since both hold different roles for authorization and to view the application process.

Note that if a PD/PI is also an HHS peer-reviewer with an Individual DUNS and CCR registration, that particular DUNS number and CCR registration are for the individual reviewer only. These are different than any DUNS number and CCR registration used by an applicant organization. Individual DUNS and CCR registration should be used only for the purposes of personal reimbursement and should not be used on any grant applications submitted to the Federal Government.

Several of the steps of the registration process could take four weeks or more. Therefore, applicants should immediately check with their business official to determine whether their organization/institution is already registered in both [Grants.gov](http://Grants.gov) and the eRA Commons. The HHS/CDC strongly encourages applicants to use the Grants.gov electronic applications process and have organizations and PD/Pis complete all necessary registrations.

## **1. Request Application Information**

Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](http://Grants.gov/Apply).

Note: Only the forms package directly attached to a specific FOA can be used. You will not be able to use any other SF424 (R&R) forms (e.g., sample forms, forms from another FOA); although some of the "Attachment" files may be useable for more than one FOA.

For further assistance, contact PGO TIMS: Telephone 770-488-2700, Email: [PGOTIM@cdc.gov](mailto:PGOTIM@cdc.gov)

HHS/CDC Telecommunications for the hearing impaired: TTY 770-488-2783.

## **2. Content and Form of Application Submission**

Prepare all applications using the SF424 (R&R) application forms and in accordance with the SF424 (R&R) Application Guide ([MS Word](#) or [PDF](#)).

The SF424 (R&R) Application Guide is critical to submitting a complete and accurate application to HHS/CDC. There are fields within the SF424 (R&R) application components that, although not marked as mandatory, are required by HHS/CDC (e.g., the "Credential" log-in field of the "Research & Related Senior/Key Person Profile"

component must contain the PD/PI assigned eRA Commons User ID). Agency-specific instructions for such fields are clearly identified in the Application Guide. For additional information, see “Tips and Tools for Navigating Electronic Submission” on the front page of “[Electronic Submission of Grant Applications](#).”

The SF424 (R&R) application is comprised of data arranged in separate components. Some components are required, others are optional. The forms package associated with this FOA in [Grants.gov/Apply](#) will include all applicable components, mandatory and optional. A completed application in response to this FOA will include the following components:

**Required Components:**

SF424 (R&R) (Cover component)  
Research & Related Project/Performance Site Locations  
Research & Related Other Project Information  
Research & Related Senior/Key Person  
Research & Related Budget  
PHS398 Cover Page Supplement  
PHS398 Research Plan  
PHS398 Checklist

**Optional Components:**

PHS398 Cover Letter File  
Research & Related Sub award Budget Attachment(s) Form

Note: While both budget components are included in the SF424 (R&R) forms package, the CDC U18 (activity code) uses ONLY the detailed Research & Related Budget. (Do not use the PHS 398 Modular Budget.)

**3. Submission Dates and Times**

See Section IV.3.A for details

**3. A. Submission, Review and Anticipated Start Dates**

Letter of Intent Receipt Date: March 1, 2010  
Application Submission Receipt Date(s): March 31, 2010  
Peer Review Date(s): May 2010  
Council Review Date(s): June 2010  
Earliest Anticipated Start Date(s): September 15, 2010  
Expiration Date: April 1, 2010

**3.A.1. Letter of Intent**

Prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this funding opportunity

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CDC Program staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed in Section IV. 3.A

The letter of intent should be sent to:

Michael Dalmat  
 Extramural Research Program Office  
 National Center for Chronic Disease Prevention and Health Promotion  
 Centers for Disease Control and Prevention  
 U.S. Department of Health and Human Services  
 Koger Center – Davidson Building (Room 1098)  
 4770 Buford Highway NE MS K-92  
 Atlanta, GA 30341  
 Telephone: (770) 488-6423  
 Fax: (770) 488-8046  
 Email: med1@cdc.gov

### **3.B. Submitting an Application to CDC**

If the instructions in this announcement differ in any way from the 424 R&R instructions, follow the instructions in this announcement.

To submit an application in response to this FOA, applicants should access this FOA via [Grants.gov/Apply](http://Grants.gov/Apply) and follow steps 1-4. If submittal of the application is done electronically through Grants.gov (<http://www.grants.gov>), the application will be electronically time/date stamped by Grants.gov. The applicants' Authorized Organization Representative (AOR) will receive an e-mail notice of receipt from eRA Commons and Grants.gov when HHS/CDC receives the application.

All requested information must be received in the HHS/CDC Procurement and Grants Office by 5:00 p.m. Eastern Standard Time on the deadline date. If an applicant submits materials by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If HHS/CDC receives your submission after closing because of : (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you have the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, HHS/CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on Letter Of Intent (LOI) and application content, submission address, and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline described in Section IV.3.A, it will not be eligible for review, and HHS/CDC will discard it. You will receive notification that you did not meet the submission requirements.

Otherwise, HHS/CDC will not notify you upon receipt of your paper submission. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIMS staff at: 770-488-2700. Before calling, please wait two to three days after the submission deadline. This will allow time for HHS/CDC to process and log submissions.

If submitting a paper application, it must be prepared using the 424 R&R instructions for preparing a research grant application. Submit a signed, typewritten original of the application and all appendices, including the checklist, and three signed photocopy(s) to the following address:

Technical Information Management Section – FOA GD10-001  
CDC, Procurements and Grants Office  
U.S. Department of Health and Human Services  
2920 Brandywine Road  
Atlanta, GA 30341  
Phone: 770-488-2700 EST

### 3.C. Application Processing

Applications **may** be submitted on or after the opening date and **must** be successfully received and validated by Grants.gov no later than **11:59 p.m. eastern time of the closing date**. If an application is not submitted by the due date(s) and time, the application may be delayed in the review process or not reviewed.

Once an application package has been successfully submitted through Grants.gov, any errors have been addressed, and the assembled application has been created in the eRA Commons, the PD/PI and the Authorized Organization Representative/Signing Official (AOR/SO) have two weekdays (Monday – Friday, excluding Federal holidays) to view the application image to determine if any further action is necessary.

- If everything is acceptable, no further action is necessary. The application will automatically move forward for processing after two weekdays, excluding Federal holidays.
- Prior to the submission deadline, the AOR/SO can “Reject” the assembled application and submit a changed/corrected application within the two-day viewing window. This option should be used if it is determined that some part of the application was lost or did not transfer correctly during the submission process, the AOR/SO will have the option to “Reject” the application and submit a Changed/Corrected application. In these cases, please contact the eRA Help Desk to ensure that the issues are addressed and corrected. Once rejected, applicants should follow the instructions for correcting errors in Section 2.12, including the requirement for cover letters on late applications. The “Reject” feature should also be used if you determine that warnings are applicable to your application and need to be addressed now. Remember, warnings do not stop further application processing. If an application submission results in warnings (but no errors), it will automatically move forward after two

weekdays if no action is taken. Some warnings may need to be addressed later in the process.

- Both the AOR/SO and PD/PI will receive e-mail notifications when the application is rejected or the application automatically moves forward in the process after two weekdays.

Note: The application is not complete until it has passed the Grants.gov validation process. Applicants will receive a submission receipt email followed by an email from Grants.gov confirming that the application package passed the validation process or was rejected due to errors. Validation takes two (2) calendar days; however, applicants may check the status of the application to ensure submission is complete. To guarantee that compliance with the Funding Opportunity Announcement, allocate additional time to the submission process. Applications that have not passed the validation process within 48 hours of the submission deadline may not be accepted. If no validation e-mail from Grants.gov is received within two (2) calendar days of submission, you may contact Grants.gov. Please refer to the Grants.gov email message generated at the time of application submission for instructions on how to track your application or the [Application User Guide](#).

Upon receipt, applications will be evaluated for completeness and responsiveness by the CDC Procurements and Grants Office and the CIO. Incomplete and non-responsive applications will not be reviewed.

There will be an acknowledgement of receipt of applications from Grants.gov and the [Commons](https://commons.era.nih.gov/commons/). The submitting AOR/SO receives the Grants.gov acknowledgments. The AOR/SO and the PI receive Commons acknowledgments. Information related to the assignment of an application to a Scientific Review Group is also in the Commons.

#### **4. Intergovernmental Review**

Executive Order 12372 does not apply to this program.

#### **5. Funding Restrictions**

All HHS/CDC awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Restrictions, which applicants must take into account while writing their budgets, are as follows:

- Funds relating to the conduct of research will be restricted until the appropriate assurances and Institutional Review Board approvals are in place.
- Reimbursement of pre-award costs is not allowed.
- Reimbursement for construction costs is not allowed

#### **6. Other Submission Requirements**

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. If submitting electronically, use a PDF version of the agreement, attach it in Grants.gov under "Other Attachments", and title it appropriately.

The Applicants' project plans should address how they will complete each of the project components: initiating the Knowledge Synthesis Center, systematic evidence reviews, topic briefs, methods documentation, and methods development over the entire project period. The plan should describe how work described under "Research Objectives and Experimental Approach" and the activities described under "Recipients Rights and Responsibilities" and "Collaborative Responsibilities" will be accomplished, and how it will incorporate EGAPP systematic review methods.

The following should be included in the application:

1. A proposed timeline of activities over the three year project period. The timeline should identify, for each project component, objective steps for project implementation and completion and dates by which those objectives will be met, given the anticipated numbers of reviews, topic briefs and other products.
2. A staffing plan describing each team member's training, expertise, and role in carrying out the objectives of the project and how the team members will complement each other's skills and work together in conducting the project, including conducting systematic evidence reviews, developing topic briefs, statistical modeling, economic evaluations, and developing methods for evaluation of new genomic technologies working with a diverse set of collaborators. The project team must include individuals who have successfully : 1) led a project team to conduct systematic evidence reviews of the analytic validity, clinical validity, and clinical utility of diagnostic, screening, or risk assessment tests/tools for clinical use, 2) evaluated genomic applications, 3) conducted statistical and/or clinical epidemiologic analysis for a) the evaluation of the clinical validity and utility of diagnostic, screening, or risk assessment tests/tools for clinical use and b) clinical decision modeling and economic analyses. The grant application and CVs of applicants must provide documentation of this experience, including previous funding and/or peer-reviewed publications in these areas.

An institution/organization may submit only one application in response to this FOA.

3. A description of how unique features of the scientific environment in which the applicant will do the work contributes to the probability of success?
4. Applicants must include costs for attending an annual GAPPNet program and three annual EGAPP Working Group meetings in their budget.

Awardees, upon acceptance of Notice of Award (NoA), must agree to the "Cooperative Agreement Terms and Conditions of Award" in Section VI. "Award Administration Information".

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age. If submitting electronically, use a PDF version of the agreement, attach it in Grants.gov under “Other Attachments”, and title it appropriately.

Applicants’ research plan(s) should address activities they will conduct over the entire project period.

The HHS/CDC requires the PD/PI to fill in his/her eRA Commons User ID in the “PROFILE – Project Director/Principal Investigator” section, “Credential” log-in field of the “Research & Related Senior/Key Person Profile” component. The applicant organization must include its DUNS number in its Organization Profile in the eRA Commons. This DUNS number must match the DUNS number provided at CCR registration with Grants.gov. For additional information, see Registration FAQs – Important Tips -- [Electronic Submission of Grant Applications](#).

### **Research Plan Component Sections**

While each section of the Research Plan component needs to be uploaded separately as a PDF attachment, applicants are encouraged to construct the Research Plan component as a single document, separating sections into distinct PDF attachments just before uploading the files. This approach will enable applicants to better monitor formatting requirements such as page limits. All attachments must be provided to HHS/CDC in PDF format, filenames must be included with no spaces or special characters, and a PDF extension must be used. Do not include any information in a header or footer of the attachments. A header will be system-generated that references the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered; therefore, do not number the pages of your attachments. Your research plan must not exceed 25 pages. If your research plan exceeds the page limitation, your application may be considered unresponsive and ineligible for review.

The following materials may be included in the Appendix:

Up to ten publications, manuscripts (accepted for publication), abstracts, patents, or other printed materials directly relevant to the proposed project. Do not include manuscripts submitted for publication. Applicants should refer to instruction guides and specific Funding Opportunity Announcements (FOAs) to determine the appropriate limit on the number of publications that may be submitted for a particular program. Note that not all grant activity codes allow the inclusion of publications.

- Publications in press: Include only a publication list with a link to the publicly available on-line journal article or the NIH Pub Med Central (PMC) submission identification number. Do not include the entire article.

- Manuscripts accepted for publication but not yet published: The entire article may be submitted electronically as a PDF attachment.
- Manuscripts published but a publicly available online journal link is not available: The entire article may be submitted electronically as a PDF attachment.
- Surveys, questionnaires, data collection instruments, clinical protocols, and informed consent documents.
- Graphic images of gels, micrographs, etc. provided that the image (may be reduced in size) is also included within the (stated) page limit of Items 2-5 of the Research Plan component. No images may be included in the Appendix that are not also represented within the Research Plan.

Please note the following restriction on appendix attachments: The Research Plan Appendix attachments are limited to 10 attachments. Appendices are uploaded as attachments in the PHS 398 Research Plan form, in field #18, within the electronic application package. An applicant will receive an error message if the number of appendix attachments exceeds 10, which will result in an unsuccessful submission of the application. You may include more than one publication, or other allowable appendix material, within one attachment; however, do not let your attachments exceed 10.”

Do not to use the Appendix to circumvent the page limitations of the Research Plan component. An application that does not observe the relevant policies and procedures may not be considered in the review process. Applicants are reminded to review specific FOAs for any additional program-specific guidance on Appendix material and other application requirements.

### **Plan for Sharing Research Data**

The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants should describe briefly the expected schedule for data sharing, the format of the final dataset, the documentation they will provide, whether or not any analytic tools also will be provided, whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not the awardee will place any conditions on their use), and the mode of data sharing (e.g., under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). References to data sharing may also be appropriate in other sections of the application.

All applicants must include a plan for sharing research data in their application. The HHS/CDC data sharing policy is available at <http://www.cdc.gov/od/pgo/funding/ARs.htm> under Additional Requirements 25 Release and Sharing of Data. All investigators responding to this funding opportunity should include a description of how final research data will be shared, or explain why data sharing is not possible.

The reasonableness of the data sharing plan or the rationale for not sharing research data will be assessed by the reviewers. However, reviewers will not factor the proposed data sharing plan into the determination of scientific merit or the priority score.

### **Sharing Research Resources**

HHS policy requires that grant award recipients make unique research resources readily available for research purposes to qualified individuals within the scientific community after publication (see the HHS Grants Policy Statement [http://www.hhs.gov/grantsnet/docs/HHSGPS\\_107.doc](http://www.hhs.gov/grantsnet/docs/HHSGPS_107.doc).) Investigators responding to this funding opportunity should include a plan for sharing research resources addressing how unique research resources will be shared or explain why sharing is not possible.

The adequacy of the resources sharing plan and any related data sharing plans will be considered by the HHS/CDC Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (PHS 2590, <http://grants.nih.gov/grants/funding/2590/2590.htm>). See [Section VI.3. Reporting](#).

## **Section V. Application Review Information**

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### **1. Criteria**

Only the review criteria described below will be considered in the review process.

### **2. Review and Selection Process**

Applications that are complete and responsive to this FOA will be evaluated for scientific and technical merit by an appropriate peer review group convened by NCCDPHP and in accordance with HHS peer review procedures (<http://grants1.nih.gov/grants/peer/>), using the review criteria stated below.

As part of the scientific peer review, all applications will:

- Undergo a selection process in which only those applications deemed to have the highest scientific and technical merit, generally the top half of applications under review, will be discussed and assigned an impact/ priority score;
- Receive a written critique; and
- Receive a second level of review by NCCDPHP

Applications submitted in response to this FOA will compete for available funds with all other recommended applications submitted in response to this FOA. The following will be considered in making funding decisions:

- Scientific merit of the proposed project as determined by peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

The [mission](#) of HHS/CDC is to promote health and quality of life by preventing and controlling disease, injury, and disability. As part of this mission, applications submitted to the HHS/CDC for grants or cooperative agreements to public health research are evaluated for scientific and technical merit through the HHS/CDC peer review system.

**Overall Impact.** Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five core review criteria, and additional review criteria (as applicable for the project proposed).

**Core Review Criteria.** Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

**Significance.** Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field? Does this research identify and fill knowledge gaps in genomics? How will this project advance public health practice?

**Investigator(s).** Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project? Do the principal investigator and other researchers have needed skills? Does the research team have experience in conducting systematic evidence reviews, statistical modeling, economic evaluations, and developing methods for evaluation of new genomic technologies? Does the team have experience working with a diverse set of collaborators?

**Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of

theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

**Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves research involving human subjects or a clinical investigation, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition to the above review criteria, the following criteria will be addressed and considered in the determination of scientific merit and the rating. The Applicants' project plans should address how they will complete each of the project components: initiating the Knowledge Synthesis Center, systematic evidence reviews, topic briefs, methods documentation, and methods development over the entire project period. The plan should describe how work described under "Research Objectives and Experimental Approach" and the activities described under "Recipients Rights and Responsibilities" and "Collaborative Responsibilities" will be accomplished, and how it will incorporate EGAPP systematic review methods.

The following should be included in the application:

1. A proposed timeline of activities over the three year project period. The timeline should identify, for each project component, objective steps for project implementation and completion and dates by which those objectives will be met, given the anticipated numbers of reviews, topic briefs and other products.
2. A staffing plan describing each team member's training, expertise, and role in carrying out the objectives of the project and how the team members will complement each other's skills and work together in conducting the project, including conducting systematic evidence reviews, developing topic briefs, statistical modeling, economic evaluations, and developing methods for evaluation of new genomic technologies working with a diverse set of collaborators. The project team must include individuals who have successfully : 1) led a project team to conduct systematic evidence reviews of the analytic validity, clinical validity, and clinical utility of diagnostic, screening, or risk assessment tests/tools for clinical use, 2) evaluated genomic applications, 3) conducted statistical and/or clinical epidemiologic analysis for a) the evaluation of the clinical validity and utility of diagnostic, screening, or risk assessment tests/tools for clinical use and b) clinical decision modeling and economic analyses. The grant application and CVs

of applicants must provide documentation of this experience, including previous funding and/or peer-reviewed publications in these areas.

**Additional Review Criteria.** As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

**Protections for Human Subjects.** The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed.

See the “Human Subjects Sections” of the PHS398 Research Plan component of the SF424 (R&R).

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements are available on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

***Inclusion of Women, Minorities, and Children.*** When the proposed project involves human subjects research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children.

Please see <http://www.cdc.gov/OD/foia/policies/inclusio.htm> for more information.

Does the application adequately address the HHS/CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits (see Section 2, item 9 Inclusion or Women and Minorities of the Research Plan component of the SF424 (R&R).

***Vertebrate Animals.*** The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and

tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

***Biohazards.*** Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

**Additional Review Considerations.** As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

***Budget and Period Support.*** Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

***Select Agent Research.*** Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

***Applications from Foreign Organizations.*** Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

***Resource and Data Sharing Plans.*** HHS/CDC policy requires that recipients of grant awards make unique research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: <http://www.cdc.gov/od/foia/policies/sharing.htm>. Investigators responding to this funding opportunity should include a plan on sharing research resources and data.

Program staff will be responsible for the administrative review of the plan for sharing research resources and data.

The adequacy of the resources and data sharing plan will be considered by Program staff of the funding organization when making recommendations about funding applications. The effectiveness of the resource sharing will be evaluated as part of the administrative review of each non-competing Grant Progress Report (HHS/PHS 2590 <http://grants.nih.gov/grants/funding/2590/2590.htm>). See Section VI.3. Reporting.

## **Section VI. Award Administration Information**

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### **1. Award Notices**

After the peer review of the application is completed, the applicant organization will receive a written critique called a “Summary Statement.” The applicant organization and the PD/PI will be able to access the Summary Statement via the eRA Commons.

HHS/CDC will contact those applicants under consideration for funding for additional information.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the Grants Management Officer (GMO) is the authorizing document. HHS/CDC will mail and/or e-mail this document to the recipient fiscal officer identified in the application.

Selection of the application for award is not an authorization to begin performance. Any cost incurred before receipt of the NoA is at the recipient’s risk. These costs may be reimbursed only to the extent considered allowable pre-award costs. See also Section IV.5. Funding Restrictions.

### **2. Administrative and National Policy Requirements**

The Code of Federal Regulations 45 CFR Part 74 and Part 92 have details about requirements. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.html>. Additional requirements are available Section VIII. Other Information of this document or on the HHS/CDC website at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>. These will be incorporated into the NoA by reference.

The following terms and conditions will be incorporated into the NoA and will be provided to the appropriate institutional official and a courteous copy to the PD/PI at the time of award.

## 2.A. Cooperative Agreement

The following terms of award are in addition to, and not in lieu of, otherwise applicable Office of Management and Budget (OMB) administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS/CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement U18 an "assistance" instrument (rather than an "acquisition" instrument), in which substantial HHS/CDC programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the HHS/CDC may share specific tasks and activities, as defined above.

### 2.A.1. Recipient Rights and Responsibilities

The Recipient will have the primary responsibility for the following:

Assuring and maintaining confidentiality of all relevant data and documents.

Ensuring that the protocol(s) is (are) conducted in compliance with the terms and conditions of human subjects protection and preparing and coordinating the submission of the protocol(s) to the grantee's IRB(s) if needed.

Maintaining an adequate management and staffing plan to support the project activities.

Attending an annual GAPPNet meeting and 3 annual EGAPP Working Group meetings.

#### Systematic Evidence Reviews

Recipient responsibilities for systematic evidence reviews include the following:

recruitment of TEP members and content experts; scheduling and setting the agenda for TEP calls;

completing evidence reviews using methods established by the EGAPP Working Group (<http://www.egapreviews.org/workingrp/methods.htm>)

organizing the external peer review, collating the comments, and making appropriate revisions in consultation with the TEP as needed.

#### Topic Briefs

completing topic briefs following the example of topic briefs available on the CDC GAPPNet web page ([www.cdc.gov/genomics/gtesting/topicbriefs/index.htm](http://www.cdc.gov/genomics/gtesting/topicbriefs/index.htm)).

summarizing information into short draft statements.

revising draft statements based on comments of internal and external stakeholders received from CDC staff

Methods development and documentation

drafting a detailed procedure manual for conducting systematic evidence reviews;

drafting a procedure manual for developing and writing topic briefs;

leading development and drafting documents for new or novel methods for conducting evidence reviews.

### **2.A.2. HHS/CDC Responsibilities**

An HHS/CDC Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

As co-investigators, CDC scientists will review PD/PIs plans, protocols, and information collection instruments, and provide technical assistance on methods for the systematic evidence reviews, sampling information sources, methods of data collection and analysis, and interpretation of study findings. CDC scientists will participate in similar fashion in development of topic briefs, methods documents, and evaluation.

CDC co-investigators may participate as co-authors in manuscript development.

CDC co-investigators will also have responsibility for the following: serving as liaison for scientific matters that may require access to CDC or other Federal subject matter experts; ensuring compliance with OMB and CDC Human Subjects Research regulations as needed;

participating in reporting of the results of the study in technical reports and at conferences.

Systematic evidence reviews

Identifying topics for review based on EGAPP Working Group requests and GAPPNet stakeholder recommendations;

Posting the analytic framework and key questions on the CDC web site for external comment;

Coordinating with the EGAPP Working Group, for reviews developed for Working Group recommendations, the development of analytic frameworks and key questions, as

well as any revisions to the analytic framework and key questions based on external comments;

Identifying experts for the Technical Expert Panel process and consulting with the Center on the TEP process;

Consulting on various aspects of the systematic review process;

Obtaining CDC clearance for web or journal publications with CDC authors;

Obtaining EGAPP Working Group review and approval for reviews developed for Working Group recommendations;

Linking or posting evidence reviews on the GAPP knowledge repository web site;

Collecting comments and questions about reviews from web users and other reviewers.

#### Topic Briefs

Identifying potential topics based on EGAPP Working Group and GAPPNet stakeholder input and defining the initial topic for review, based on the medical disorder, the specific genomic application, the proposed purpose of the test, and clinical scenario for use of the service;

Providing the Center with information and data already obtained by CDC through prior searches on the topic;

Reviewing draft topic brief summaries, providing feedback and proposing any necessary revisions

Approval of finalized topic briefs and posting the documents on the GAPP knowledge repository site;

Providing the Center with comments and questions received from web users and other stakeholders on the topics briefs, and proposing revisions based on this feedback.

#### **Methods development**

Providing technical assistance during the development and drafting of procedure manuals for conducting systematic evidence reviews, developing and writing topic briefs and other methods documents

Additionally, an HHS/CDC agency program official or CIO program director will be responsible for the normal scientific and programmatic stewardship of the award and will

be named in the NoA. The CDC ERPO/CCHP will appoint a Scientific Program Official (SPO) who will:

1. Serve as the Program Official for the funded site.
2. Carry out continuous review of all activities to ensure objectives are being met.
3. Attend committee meetings and participate in conference calls for the purposes of assessing overall progress and for program evaluation purposes.
4. Provide scientific consultation and technical assistance in the conduct of the project as requested.
5. Conduct site visits to determine the adequacy of the research.
6. Monitor performance against approved project objectives.

### **2.A.3. Collaborative Responsibilities**

CDC scientists and PD/PIs will participate in regularly scheduled conference calls and site visits to monitor progress of the projects and participate in program planning.

CDC scientists and PD/PIs will participate in an annual GAPPNet meeting and 3 annual EGAPP Working Group meetings.

Developing a coordinated work plan, milestones, and timeline at the beginning of each project year for work that will be accomplished during that year, including the following: systematic evidence reviews, topic briefs, methods dissemination, and methods development

#### **Systematic evidence reviews**

Defining objectives and approaches to implement the reviews;

Refining the topic for review, based on EGAPP Working Group and CDC priorities for the medical disorder, the specific genetic test or service, and clinical scenario for use of the service; and background information searching;

Developing and finalizing analytic frameworks and framing the specific key questions for which evidence is collected and reviewed;

Evaluating the overall strength and quality of evidence related to the analytic framework, or where direct evidence is lacking, establish a chain of evidence, and evaluating each link in that chain;

Planning the peer review;

Finalizing each evidence review along with a corresponding manuscript for journal publication summarizing each review.

## **Topic Briefs**

Developing search criteria and strategies;

Finalizing the topic briefs for posting on the GAPPNet web site;

## **Methods dissemination and development**

Defining objectives and approaches to implement the reviews;

Finalizing the procedure manuals for conducting systematic evidence reviews for the EGAPP Working Group and for developing topic briefs;

Planning and developing additional procedures and methods to build upon those previously developed by the EGAPP Working Group.

Recipient Organization will retain custody of and have primary rights to the information, data and software developed under this award, subject to U.S. Government rights of access consistent with current HHS/CDC policies.

## **3. Reporting**

1. Recipient Organization must provide HHS/CDC with an original, plus two hard copies of the following reports:
2. Non-Competing Grant Progress Report, (use form PHS 2590, posted on the HHS/CDC website, <http://www.cdc.gov/od/pgo/funding/forms.htm> and at <http://grants.nih.gov/grants/funding/2590/2590.htm>, no less than 120 days prior to the end of the current budget period. The progress report will serve as the non-competing continuation application.
3. Financial status report, no more than 90 days after the end of the budget period.
4. Final financial and performance reports, no more than 90 days after the end of the project period.

Recipient Organization must forward these reports by the U.S. Postal Service or express delivery to the Grants Management Specialist listed in the “Agency Contacts” section of this FOA.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

## **Section VII. Agency Contacts**

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HHS/CDC encourages your inquiries concerning this FOA and welcomes the opportunity to answer questions from potential applicants. Inquiries can fall into three areas:

scientific/research, peer review, and financial or grants management issues:

### **1. Scientific/Research Contacts:**

Michael Dalmat  
Extramural Research Program Office  
National Center for Chronic Disease Prevention and Health Promotion  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
Koger Center – Davidson Building (Room 1098)  
4770 Buford Highway NE MS K-92  
Atlanta, GA 30341  
Telephone: (770) 488-6423  
Fax: (770) 488-8046  
Email: med1@cdc.gov

### **2. Peer Review Contacts:**

External Research Program Office  
Coordinating Center for Health Promotion  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services  
MS K92  
4770 Buford Highway NE  
Atlanta, GA 30341  
Telephone: (770) 488-8390  
Email: CDC NCCD/ERO@cdc.gov

### **3. Financial or Grants Management Contacts:**

Veronica Davis  
Procurement and Grants Office  
Center for Disease Control and Prevention  
U.S. Department of Health and Human Services  
Building Number, Room Number  
Street Address  
Atlanta, GA Zip Code  
Telephone: (770) 488.2743  
Fax: 770.488.2777  
Email: [vad4@cdc.gov](mailto:vad4@cdc.gov)

### **4. General Questions Contacts:**

Technical Information Management Section

CDC Procurement and Grants Office  
U.S. Department of Health and Human Services  
2920 Brandywine Road  
Atlanta, GA 30341  
Telephone: 770-488-2700  
Email: PGOTIM@cdc.gov

## Section VIII. Other Information

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### Required Federal Citations

#### Human Subjects Protection

Federal regulations (45 CFR Part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>). Additional HHS/CDC Requirements under AR-1 Human Subjects Requirements can be found on the Internet at the following address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

#### Use of Animals in Research

Recipients of PHS support for activities involving live, vertebrate animals must comply with the PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>) as mandated by the Health Research Extension Act of 1985 (<http://grants.nih.gov/grants/olaw/references/hrea1985.htm>), and the USDA Animal Welfare Regulations (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>) as applicable. Additional HHS/CDC Requirements under AR-3 Animal Subjects Requirements can be found ~~on~~ at <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

#### Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

## **INCLUSION OF PERSONS UNDER THE AGE OF 21 IN RESEARCH**

The policy of CDC is that persons under the age of 21 must be included in all human subjects research that is conducted or supported by CDC, unless there are scientific and ethical reasons not to include them. This policy applies to all CDC-conducted or CDC-supported research involving human subjects, including research that is otherwise exempt in accordance with Sections 101(b) and 401(b) of 45 C.F.R. Part 46, HHS Policy for the Protection of Human Subjects. Therefore, proposals for research involving human subjects must include a description of plans for including persons under the age of 21. If persons under the age of 21 will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In an extramural research plan, the investigator should create a section titled "Participation of persons under the age of 21." This section should provide either a description of the plans to include persons under the age of 21 and a rationale for selecting or excluding a specific age range, or an explanation of the reason(s) for excluding persons under the age of 21 as participants in the research. When persons under the age of 21 are included, the plan must also include a description of the expertise of the investigative team for dealing with individuals at the ages included, the appropriateness of the available facilities to accommodate the included age groups, and the inclusion of a sufficient number of persons under the age of 21 to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at CDC will assess each application as being acceptable or unacceptable in regard to the age-appropriate inclusion or exclusion of persons under the age of 21 in the research project, in addition to evaluating the plans for conducting the research in accordance with these provisions.

The inclusion of children (as defined by the applicable law of the jurisdiction in which the research will be conducted) as subjects in research must be in compliance with all applicable subparts of 45 C.F.R. Part 46, as well as with other pertinent federal laws and regulations.

The policy of inclusion of persons under the age of 21 in CDC-conducted or CDC-supported research activities in foreign countries (including collaborative activities) is the same as that for research conducted in the United States.

## **HIV/AIDS Confidentiality Provisions [Not Applicable]**

Recipients must have confidentiality and security provisions to protect data collected through HIV/AIDS surveillance, including copies of local data release policies; employee training in confidentiality provisions; State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information.

Describe laws, rules, regulations, or health department policies that require or permit the release of patient-identifying information collected under the HIV/AIDS surveillance system to entities outside the public health department; describe also the measures the health department has taken to ensure that persons reported to the surveillance system are protected from further or unlawful disclosure.

Some projects may require Institutional Review Board (IRB) approval or a certificate of confidentiality.

**HIV Program Review Panel Requirements [Not applicable]**

Compliance with Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (June 1992) is required.

To meet the requirements for a program review panel, you are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If you form your own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. List the names of the review panel members on the Assurance of Compliance form, CDC 0.1113. Submit the program review panel's report that all materials have been approved.

If the proposed project involves hosting a conference, submit the program review panel's report stating that all materials, including the proposed conference agenda, have been approved. Submit a copy of the proposed agenda with the application. Before funds are used to develop educational materials, determine whether suitable materials already exist in the CDC National Prevention Information Network (NPIN). The website can be found at; <http://www.nchstp.cdc.gov/od/infocenter/npin.htm>.

**Patient Care [Not applicable]**

Ensure that all STD or HIV infected patients enrolled in the proposed project will be linked to an appropriate local care system that can address their specific needs, such as medical care, counseling, social services, and therapy.

**Executive Order 12372 Review [Not applicable]**

Applications are subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (E.O.) 12372. The order sets up a system for State and local governmental review of proposed Federal assistance applications. Applicants should contact their State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications and to receive instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each State affected.

Click on the following link to get the current SPOC list

<http://www.whitehouse.gov/omb/grants/spoc.html>

Indian tribes must request tribal government review of their applications.

Specs or tribal governments that have recommendations about an application submitted to HHS/CDC should send them, in a document bearing the program announcement number, no more than 60 days after the application deadline date, to:

Veronica Davis, Grants Management Specialist  
Procurement and Grants Office  
Announcement Number RFA-DD10-007  
Centers for Disease Control and Prevention (CDC)  
2920 Brandywine Road  
Atlanta, Georgia 30341-4146

HHS/CDC does not guarantee to accept or justify its non-acceptance of recommendations that are received more than 60 days after the application deadline.

**Public Health System Reporting Requirements**

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

- A. A copy of the face page of the application (SF 424).
  
- B. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:
  - 1. A description of the population to be served.
  - 2. A summary of the services to be provided.
  - 3. A description of the coordination plans with the appropriate state and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

**Paperwork Reduction Act Requirements**

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant or a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).

**Smoke-Free Workplace Requirements**

HHS/CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

## **Healthy People 2010**

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at [www.healthypeople.gov](http://www.healthypeople.gov)

## **Lobbying Restrictions**

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of HHS/CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, HHS/CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation

It remains permissible to use HHS/CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of HHS/CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of HHS/CDC funds should give close attention to isolating and separating the appropriate use of HHS/CDC funds from non-CDC funds. HHS/CDC also cautions recipients of HHS/CDC funds to be careful not to give the appearance that HHS/CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

### **Prohibition on Use of HHS/CDC Funds for Certain Gun Control Activities**

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control."

Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, HHS/CDC interprets the language in the HHS/CDC's Appropriations Act to mean that HHS/CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

### **Accounting System Requirements**

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

### **Capability Assessment**

It may be necessary to conduct an on-site evaluation of some applicant organization's financial management capabilities prior to or immediately following the award of the grant or cooperative agreement. Independent audit statements from a Certified Public Accountant (CPA) for the preceding two fiscal years may also be required.

### **Proof of Non-profit Status**

Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit status: (a) a reference to the applicant organization's listing in the Internal Revenue Service's (IRS)

most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate; (c) a statement from a State taxing body, State Attorney General, or other appropriate State Official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status; (e) any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

**Security Clearance Requirement [Not applicable]**

All individuals who will be performing work under a grant or cooperative agreement in a HHS/CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardees employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at HHS/CDC must undergo a security clearance process.

**Peer and Technical Reviews of Final Reports of Health Studies – HHS/ATSDR**

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by Superfund Amendments and Reauthorization Act of 1986 (SARA), Section 104 (I)(13), and [42 U.S.C. 9604 (I)] requires all studies and results of research (other than public health assessments) that ATSDR carries out or funds in whole or in part will be peer reviewed by ATSDR. The ATSDR peer review process for final reports requires that:

1. Studies must be reported or adopted only after appropriate peer review.
2. Studies shall be peer reviewed within a period of 60 days to the maximum extent practical.
3. Studies shall be reviewed by no fewer than three or more than seven reviewers who:
  - a. Are selected by the Assistant Administrator, ATSDR;
  - b. Are disinterested scientific experts;
  - c. Have a reputation for scientific objectivity; and
  - d. Who lack institutional ties with any person involved in the conduct of the study or research under review.

HHS/ATSDR encourages rapid reporting and interpretation of laboratory results and reference ranges back to individual participants. However, if summary tables or distribution of laboratory results are prepared using the study data, this is considered a preliminary finding and will require ATSDR technical and peer review prior to release. When, in the opinion of the investigator(s), a public health concern exists requiring the release of summary study statistics prior to the completion of the study, the investigator

must obtain concurrence from HHS/ATSDR prior to releasing the summary statistics. A request for HHS/ATSDR concurrence for the release of information must be documented in a letter to HHS/ATSDR and should outline the public health concern, the investigator's interpretation of the concern and recommended response, and the draft document proposed for release by the investigator. HHS/ATSDR will provide a technical review and peer review within ten working days to the maximum extent possible. At sites where HHS/ATSDR must coordinate with another Federal agency, this requires additional time. Summary statistics may be released only after peer review. The release of summary statistics does not preclude the requirement for a final report.

By statute, the reporting of preliminary studies and preliminary research results to the public is not acceptable without prior review by HHS/ATSDR. This includes manuscripts prepared for publication, presentations at scientific meetings and reporting of preliminary findings to the community or the media.

### Final Report

1. The final report for every study should include a detailed description of the problem, hypothesis, methods, results, conclusions, and recommendations that constitute a complete performance record of the study. A copy of the suggested format for the final report will be supplied by HHS/ATSDR to the investigator.
2. HHS/ATSDR is responsible for the technical and peer review of the draft final reports of any study that it funds prior to the submission of the final report. This will allow the recipient to incorporate technical and peer review comments into the final report. Responses to all HHS/ATSDR required technical and peer review comments should be summarized in a letter to HHS/ATSDR. This letter should also include the investigator's response to each comment and a rationale for those responses. Based upon the comments of the technical and peer reviewers, modifications in the study report may result. The modified study report should accompany the letter to HHS/ATSDR.
3. Following the steps outlined above, a final report of all studies and results of research carried out or supported by HHS/ATSDR must be submitted to the Procurement and Grants Office with a copy furnished to HHS/ATSDR.

All requirements, including peer review, technical review, and cost recovery, are applicable to award recipients and any subcontractors employed by the award recipient. Failure to comply with these requirements could adversely affect future funding.

### **Cost Recovery – HHS/ATSDR**

CERCLA, as amended by SARA, provides for the recovery of costs incurred for response actions at each Superfund site from potentially responsible parties. The recipient would

agree to maintain an accounting system that will keep an accurate, complete, and current accounting of all financial transactions on a site-specific basis, i.e., individual time, travel, and associated cost including indirect cost, as appropriate for the site. The recipient would also maintain documentation that describes the site-specific response actions taken with respect to the site, e.g., contracts, work assignments, progress reports, and other documents that describe the work performed at a site. The recipient will provide the site-specific costs and description of response actions taken with the supporting documentation upon request by HHS/ATSDR. The recipient will retain the documents and records to support these financial transactions and documentation of work performed, for possible use in a cost recovery case, for a minimum of ten years after submission of a final financial status report, unless there is litigation, claim, negotiation, audit or other action involving the specific site, then the records will be maintained until resolution of all issues on the specific site.

### **Third Party Agreements – HHS/ATSDR**

Applicant must justify the need to use a contractor. If contractors are proposed, the following must be provided: (1) name of contractor, (2) method of selection, (3) period of performance, (4) detailed budget, (5) justification for use of contractor, and (6) assurance of non-conflict of interest.

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly establishes the relationship between the recipient and the third party.

The written agreement shall, at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the terms of the grant and/or cooperative agreement, including requirements concerning technical review (ATSDR selected reviewers), ownership of data, and the arrangement for copyright when publications, data, or other copyrightable works are developed under or in the course of work under a PHS grant-supported project or activity.
2. State that any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal government purposes.
3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under a grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the government's right in that work.
4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the

agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.

5. State non-conflict of interest concerning activities conducted for HHS/ATSDR and site-remediation activities for other parties.

The written agreement required shall not relieve the recipient of any part of its responsibility or accountability to PHS under the cooperative agreement. The agreement shall, therefore, retain sufficient rights and control to the recipient to enable it to fulfill this responsibility and accountability.

### **Small, Minority, And Women-owned Business**

It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

1. Place small, minority, women-owned business firms on bidders mailing lists.
2. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.
3. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.
4. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

### **Research Integrity**

The signature of the institution official on the face page of the application submitted under this Funding Opportunity Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 93, Subparts A-E, entitled PUBLIC HEALTH SERVICE POLICIES ON RESEARCH MISCONDUCT.

The regulation places requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity (ORI) (<http://ori.hhs.gov/policies/statutes.shtml>).

For example:

Section 93.301 Institutional assurances. (a) General policy. An institution with PHS supported biomedical or behavioral research, research training or activities related to that research or research training must provide PHS with an assurance of compliance with this part, satisfactory to the Secretary. PHS funding components may authorize [[Page 28389]] funds for biomedical and behavioral research, research training, or activities related to that research or research training only to institutions that have approved assurances and required renewals on file with ORI. (b) Institutional Assurance. The

responsible institutional official must assure on behalf of the institution that the institution-- (1) Has written policies and procedures in compliance with this part for inquiring into and investigating allegations of research misconduct; and (2) Complies with its own policies and procedures and the requirements of this part.

### **Compliance with Executive Order 13279**

Faith-based organization are eligible to receive federal financial assistance, and their applications are evaluated in the same manner and using the same criteria as those for non-faith-based organizations in accordance with Executive Order 13279, Equal Protection of the Laws for Faith-Based and Community Organizations. All applicants should, however, be aware of restrictions on the use of direct financial assistance from the Department of Health and Human Services (DHHS) for inherently religious activities. Under the provisions of Title 45, Parts 74, 87, 92 and 96, organizations that receive direct financial assistance from DHHS under any DHHS program may not engage in inherently religious activities, such as worship, religious instruction, or proselytization as a part of the programs or services funded with direct financial assistance from DHHS. If an organization engages in such activities, it must offer them separately, in time or location, from the programs or services funded with direct DHHS assistance, and participation must be voluntary for the beneficiaries of the programs or services funded with such assistance. A religious organization that participates in the DHHS funded programs or services will retain its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from DHHS to support inherently religious activities such as those activities described above. A faith-based organization may, however, use space in its facilities to provide programs or services funded with financial assistance from DHHS without removing religious art, icons, scriptures, or other religious symbols. In addition, a religious organization that receives financial assistance from DHHS retains its authority over its internal governance, and it may retain religious terms in its organization=s name, select its board members on a religious basis, and include religious references in its organization=s mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of DHHS funded activities. For further guidance on the use of DHHS direct financial assistance see Title 45, Code of Federal Regulations, Part 87, Equal Treatment for Faith-Based Organizations, and visit the internet site:

<http://www.whitehouse.gov/government/fbci/>

### **Health Insurance Portability and Accountability Act Requirements**

Recipients of this grant award should note that pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR Parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority

includes a person or entity acting under a grant of authority from or contract with such public agency. HHS/CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and HHS/CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

### **Release and Sharing of Data**

The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the HHS/CDC data sharing agreement will be released as follows:

- a. In a timely manner.
- b. Completely, and as accurately as possible.
- c. To facilitate the broader community.
- d. Developed in accordance with CDC policy on Releasing and Sharing Data.

April 16, 2003, <http://www.cdc.gov/od/foia/policies/sharing.htm>, and in full compliance with the 1996 Health Insurance Portability and Accountability Act (HIPPA), (where applicable), The Office of Management and Budget Circular A110, (2000) revised 2003, [www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data](http://www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data) and Freedom of Information Act (FOIA) <http://www.cdc.gov/od/foia/index.htm>.

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide HHS/CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program Manager will determine the documentation format. HHS/CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

### **National Historic Preservation Act of 1966**

#### **(Public Law 89-665, 80 Stat. 915)**

The grantee's signature on the grant application attests to their: (1) knowledge of the National Historic Preservation Act of 1966 (Public Law 89-665, 80 Stat. 915); and (2) intent to ensure all grant related activities are in compliance with referenced public law, as stated:

- a. Section 106 of the National Historic Preservation Act (NHPA) states:

*The head of any Federal agency, having direct or indirect jurisdiction over a proposed Federal or Federally assisted undertaking in any State and the head of any Federal department or independent state agency having authority to license any undertaking, shall, prior to the approval of the expenditure of any Federal funds on the undertaking or prior to the issuance of any license, as the case may be, take into account the effect of the undertaking on any district, site, building, structure, or*

*object that is included in or is eligible for inclusion in the National Register. The head of any such Federal agency shall afford the Advisory Council on Historic Preservation established under Title II of this ACT a reasonable opportunity to comment with regard to such undertaking.*

- b. Additionally, the NHPA also contains the following excerpt that forbids “anticipatory demolition:”

*Each Federal agency shall ensure that the agency will not grant a loan, loan guarantee, permit, license, or other assistance to an applicant who, with intent to avoid the requirements of Section 106 of this Act, has intentionally, significantly, adversely affected a historic property to which the grant would relate or, having power to prevent it, allowed such significant adverse effect to occur, unless the agency, after consultation with the Council, determines that circumstances justify granting such assistance despite the adverse effect created or permitted by the applicant.*

#### **Conference Disclaimer and Use of Logos**

{Mandatory for all grants and cooperative agreements. }

**Disclaimer:** Where a conference is funded by a grant or cooperative agreement, a sub grant or a contract the recipient must include the following statement on conference materials, including promotional materials, agenda, and internet sites:

*“Funding for this conference was made possible [in part] by [insert grant or cooperative agreement award number] from the Centers for Disease Control and Prevention(CDC) or the Agency for Toxic Substances and Disease Registry (ATSDR) . The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does mention of trade names, commercial practices, or organizations imply endorsement by the U.S. Government.”*

**Logos:** Neither the HHS nor the CDC (“CDC” includes ATSDR) logo may be displayed if such display would cause confusion as to the source of the conference or give the false appearance of Government endorsement. A non-federal entity’s unauthorized use of the HHS name or logo is governed by U.S.C. § 1320b-10, which prohibits the misuse of the HHS name and emblem in written communication. The appropriate use of the HHS logo is subject to the review and approval of the Office of the Assistant Secretary for Public Affairs (OASPA). Moreover, the Office of the Inspector General has authority to impose civil monetary penalties for violations (42 C.F.R. Part 1003). Neither the HHS nor the CDC logo can be used on conference materials under a grant, cooperative agreement, contract or co-sponsorship agreement without the expressed, written consent of either the Project Officer or the Grants Management Officer. It is the responsibility of the grantee (or recipient of funds under a cooperative agreement) to request consent for the use of the logo in sufficient detail to assure a complete

depiction and disclosure of all uses of the Government logos, and to assure that in all cases of the use of Government logos, the written consent of either the Project Officer or the Grants Management Officer has been received.